



**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

NEXUS PHARMACEUTICALS, INC.,
Plaintiff,

vs.

NEPHRON SC, INC.,
Defendant.

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CIVIL ACTION No. 3:22-cv-137-MGL

**MEMORANDUM OPINION AND ORDER
DENYING DEFENDANT’S MOTION TO DISMISS AND LIFTING STAY**

I. INTRODUCTION

Plaintiff Nexus Pharmaceuticals, Inc (Nexus) brings this action against Defendant Nephron SC, Inc (Nephron). Nexus’s complaint alleges infringement of U.S. Patent No. 11,090,278 (Patent ‘278) under 35 U.S.C. § 271(e)(2). The Court has jurisdiction under 28 U.S.C. § 1331.

Pending before the Court is Nephron’s motion to dismiss Nexus’s complaint under Fed. R. Civ. P. 12(b)(6). Having carefully considered the motion, the response, the reply, the record, and the applicable law, it is the judgment of the Court the motion to dismiss will be denied and the stay of discovery in this case will be lifted.

II. FACTUAL AND PROCEDURAL HISTORY

Nexus’s complaint alleges Nephron violated Patent ‘278 by seeking to market a generic version of EMERPHED, Nexus’s ephedrine injection drug, before the expiration of the patent. Patent ‘278 covers the methods of administering EMERPHED. Nexus also owns a New Drug

Application for EMERPHED itself. Nephron describes its generic version in Abbreviated New Drug Application No. 216313 (ANDA).

Nexus contends Nephron applied for and intends to distribute its drug before the expiration of Nexus's patent. The drug allegedly contains the same formulation as EMERPHED, has the same chemical properties as EMERPHED, will be manufactured in an equivalent process and an equivalent container to EMERPHED, and will contain a package insert substantially the same as EMERPHED. But, Nephron's generic version would use vials made of high temperature low density polyethylene (HT LDPE), while EMERPHED uses glass vials.

Nexus filed this action and Nephron moved to dismiss. Nexus responded, and Nephron replied. The Court stayed discovery pending ruling on the motion. The Court, having been fully briefed on the relevant issues, will now adjudicate the motion.

III. STANDARD OF REVIEW

A party may move to dismiss a complaint based on its "failure to state a claim upon which relief may be granted." Fed. R. Civ. P. 12(b)(6). "The purpose of a Rule 12(b)(6) motion is to test the sufficiency of a complaint[.]" *Edwards v. City of Goldsboro*, 173 F.3d 231, 243 (4th Cir. 1999). To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim, a complaint must have "enough facts to state a claim to relief that is plausible on its face[.]" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), and contain more than "an unadorned, the-defendant-unlawfully-harmed-me accusation[.]" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *see also Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (explaining in the context of pleading patent infringement, the complaint must put the defendant "on notice of what activity is being accused of infringement." (internal ellipsis omitted)).

In considering a motion to dismiss for failure to state a claim, “the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff.” *Mylan Lab ’ys v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993). But, the Court need not “accept as true the legal conclusions set forth in a plaintiff’s complaint.” *Edwards*, 178 F.3d at 243.

IV. DISCUSSION AND ANALYSIS

A. Whether the Court will consider the additional materials included by Nephron in its motion

Nephron first asks this Court to consider the ANDA and the Notice Letter to Nexus of the ANDA. In response, Nexus argues these materials are improper to consider at this stage of the case.

Courts may also consider documents attached to the motion “so long as they are integral to the complaint and authentic[.]” *Sec’y of State for Def. v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007). To be integral to the complaint, a document must do more than contain information that is important to the plaintiff’s claims. Instead, its very existence must give rise to the legal rights asserted. *See United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 106 (2d Cir. 2021) (“For a document to be considered integral to the complaint, the plaintiff must rely on the terms and effect of a document in drafting the complaint.” (internal quotation marks omitted)).

1. Whether the Court will consider the ANDA

First, Nephron asks the Court to consider a page of its ANDA, which it attaches to its motion. The page specifically details the HT LDPE vial Nephron intends to use. The ANDA also describes Nephron’s rationale for choosing plastic vials over glass vials in developing its product. Nexus contends that the mere reference to the ANDA in the complaint fails to render the document

integral to it. Alternatively, Nexus argues, even if the Court considers the ANDA, it should refuse to assess the validity of the technical descriptions or other facts alleged within it.

Here, Nexus fails to challenge the authenticity of the ANDA itself, only that it is integral to the complaint. In the complaint, however, Nexus repeatedly references the ANDA in support of its infringement claim. The existence of the ANDA is the sole reason Nexus filed suit against Nephron to protect its patent, and thus is integral to the complaint.

The Court will therefore consider the ANDA.

2. *Whether the Court will consider the Notice Letter*

Second, Nephron asks this Court to consider its Notice Letter of submission of the ANDA (the Notice Letter), which it attaches to its reply, because Nexus was already in possession of the document and “relied upon it when drafting its Complaint.” Nephron’s Reply at 9.

Unlike the ANDA, the Notice Letter is only briefly referenced in Nexus’s complaint and mentioned only to inform the court of how Nexus came to be aware of Nephron’s ANDA. It is not integral to the complaint, nor does it give rise to the legal rights asserted. Thus, the Court declines to consider the Notice Letter for purposes of this motion.

B. *Whether the Court will take judicial notice of the definitions of polypropylene and polyethylene*

Nephron also asks the Court to take judicial notice that polypropylene and polyethylene are plastics. Nexus argues both these definitions are purely extraneous and should not be considered at this stage of litigation.

Nexus’s complaint fails to mention polypropylene or polyethylene. The Court declines any invitation to pretend to be an expert in the chemical intricacies that determine the scientific—rather than everyday—classification of materials.

Having cited only to Encyclopedia Britannica articles for polypropylene or polyethylene, Nephron fails to provide sufficient information for the Court to determine whether they qualify as plastics in this context. *See* Fed. R. Evid. 201(b)(2) (explaining the Court may take judicial notice of “a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned”). The Court therefore declines to take judicial notice of Nephron’s claim.

C. Whether the court will grant the motion to dismiss

The Court now turns to the substance of Nephron’s motion. Nephron posits the disclosure-dedication rule bars Nexus from making a claim for patent infringement under the doctrine of equivalents because Nexus failed to claim plastic vials in Patent ‘278.

The doctrine of equivalents operates to protect the patentee from near-identical products with only minute and insignificant variations. *Id.* at 608. Determining whether something is an equivalent is a question of fact and is not limited to subject matter disclosed in the patent itself. *Id.* at 609.

The disclosure-dedication rule, however, limits what constitutes patent infringement under the doctrine of equivalents. *Johnson & Johnson Assocs Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Under the rule, subject matter disclosed as part of the patent information by the patentee, but not claimed as part of the patent, is considered dedicated to the public. *Id.*

If “one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public.” *PSC Comput. Prod., Inc. v. Foxconn Int’l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). “The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.” *Id.*; *cf. Eli Lilly and Co. v. Hospira, Inc.*, 933

F.3d 1320, 1334 (Fed. Cir. 2019) (rejecting the application of the dedication-disclosure rule on a motion for summary judgment because the alleged dedication was unspecific).

Nexus disagrees with Nephron, arguing Patent ‘278 fails to explicitly disclose HT LDPE, and thus, it was undedicated to the public. It contends the doctrine of equivalents thus renders Nephron’s product in violation of the law.

A claim for patent infringement requires allegations of either literal infringement or infringement under the doctrine of equivalents. In this case, it appears Nexus has conceded there is not literal infringement. *See Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950) (“Outright and forthright duplication [of a patent] is a dull and very rare type of infringement.”). The Court will thus analyze the motion under the doctrine of equivalents.

Here, in Patent ‘278, Nexus mentions both glass and plastic as alternatives for vials in the patent information, but lists only glass under the claims section. Patent ‘278 fails to mention HT LDPE specifically. As noted above, determining what classifies as plastic, for the purposes of this patent infringement, is not necessarily obvious.

This issue is thus best decided at the summary judgment stage. *See PSC Comput. Prod., Inc.*, 355 F.3d at 1360 (applying the disclosure-dedication rule in a motion for summary judgment). Accordingly, the Court will deny Nephron’s motion to dismiss.

V. CONCLUSION

For the reasons stated above, it is the judgment of the Court Nephron’s motion to dismiss is **DENIED**. The stay in this case is hereby **LIFTED**. The parties shall submit a joint proposed amended scheduling order no later than one week from the date of this order.

IT IS SO ORDERED.

Signed this 8th day of November 2022, in Columbia, South Carolina.

s/ Mary Geiger Lewis
MARY GEIGER LEWIS
UNITED STATES DISTRICT JUDGE